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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/732,890 | 12/10/2003 | James R. Lisk JR. | 5N03.1-011 | 6906 |
| 23506 7590 06/26/2008 GARDNER GROFF GREENWALD & VILLANUEVA, PC 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339 | | | EXAMINER MENDOZA, MICHAEL G | |
| | | | ART UNIT 3734 | PAPER NUMBER |
| | | | MAIL DATE 06/26/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,890

Applicant(s)

LISK ET AL.

Examiner

MICHAEL G. MENDOZA

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3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-25 and 31-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-25 and 31-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/9/2008 have been fully considered but they are not persuasive.
2. The applicant argues the blade of Ours and the blade of the instant application are functionally different. The blade of Ours meets the structure limitations of the device claims, e.g. a polymeric separating edge that is blunt. The recitation that the separator is "for use with a surgical device...." has not been patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). Furthermore, the function recitation that "so that it separates corneal epithelium from Bowman's layer..." has not been given patentable weight because it is narrative in form. In order to be given patentable weight, a function recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. The claim limitations give no structural limitation to differentiate the blade of Ours from the instant application.
3. The applicant argues that the blade of Pallikaris et al. and the blade of Foggia et al. are from different surgical arts. The examiner disagrees. Both blades have an edge for cutting and are therefore in similar surgical arts. Foggia et al. also teaches the use

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of a polymer blade that is not brittle over a metal blade, and that they are mechanical expedients.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3-25, and 31-43 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 and 37-41 of copending Application No. 10/737,533. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations in the instant application are also claimed in the copending application, e.g. a positioning ring, and a separator having a separating edge.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ours 4048471.

8. Ours teaches a separator comprising a polymeric separating edge, wherein the polymeric separating edge comprises a fluoropolymer (polytetrafluoroethylene, see claim 8).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 16-20 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Ours.

11. Ours teaches the claimed invention except for the properties of the polymeric material. Ours et al. teaches the use of polymers (col. 2, lines 36-43). These polymers are also recited in the claim limitations and can be made with the same recited properties. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymer having the recited structural properties, since

it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

12. Claims 1, 3, 8, 13-20, 25, and 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris et al. 7004953 in view of Foggia et al 5782852.

13. As to claims 1, 14, 31, 32, Pallikaris et al. teach a surgical device comprising: a positioning ring; and a separator assembly including a separator having a blunt separating edge; wherein the radius of curvature of the separating edge of the separator is between 5 micron and about 100 microns, or 10 microns and about 30 microns, or 15 microns and 25 microns (col. 6, lines 22-29); wherein the polymeric separating edge is flat, wherein the polymeric separating edge is rounded, wherein the polymeric separating edge includes an angled point (see fig. 23).

14. Pallikaris et al. teaches that the blade can be manufactured from a material that is strong enough to push epithelium without breaking. It should be noted that Pallikaris fails to teach the preferred materials and their properties. It is known in the art to use a polymeric blade in place of a metal blade in the surgical art as evidenced by Foggia et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymeric blade as taught by Foggia et al. as a mechanical expedient to a metal blade (see entire reference).

15. As to claims 3-8, 15-20, 25, 33, 34 Pallikaris/Foggia teaches the claimed invention except for the properties of the polymeric material. Foggia et al. teaches the use of polymers (col. 5, lines 21-25). These polymers are also recited in the claim limitations and can be made with the same recited properties. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to use a polymer having the recited structural properties, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

16. As to claim 36 and 37, Pallikaris et al. teaches a metal blade. It should be noted that Pallikaris et al. fails to teach a polymer coating on the edge of the blade. However, it is well known in the art of blades to coat the edge of a blade with a polymer, e.g., Teflon, for hardening, anticorrosive properties, or as a lubricative layer for the metal blade. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a polymer coating to the edge of the blade of Pallikaris et al. to enhance the properties of the blade.

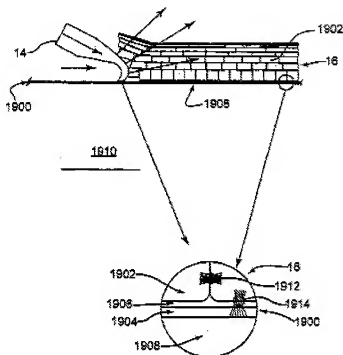


FIG. 19

17. Claims 9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Samuels et al. 6247389.

18. Pallikaris/Foggia teaches the surgical device as claimed in claim 1.

Pallikaris/Foggia teaches the use of a non-brittle polymer blade. Samuels et al. teaches the use of fillers (glass fiber and carbon fiber) for reinforcing polymer blades. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the fillers in view of Samuels et al. to reinforce the polymer blades to make them less brittle.

19. Claim 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Feingold 6083236.

20. Pallikaris/Foggia teaches the surgical device as claimed in claim 1. It should be noted that Pallikaris/Foggia fails to teach wherein the polymeric edge comprises a transparent material. However, Feingold teaches the use of a transparent blade (col. 6, lines 24-25). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the polymeric blade of Pallikaris/Foggia transparent for the best visibility during the process of separation.

21. As to claim 41, Pallikaris/Foggia teaches the claimed invention except for the leading edge portion size range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed range limitations, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

22. Claims 11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pallikaris/Foggia in view of Scwemberger et al. 5569292.

23. As to claims 11 and 23, Pallikaris/Foggia/Feingold teaches the device as claimed in claim 10 and 22. It should be noted the that the above combination fails to disclose a light transmission greater than about 50, and a haze factor less the 25 percent. However, Scwemberger teaches the use of a surgical blade of a plastics material with similar limitations that does not obstruct the visual field during operation (col. 7, lines 14-17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the light transmission and haze factor for viewing in view of Scwemberger.

24. As to claims 12 and 24, the above combination teaches the device of claim 10. It should be noted that the combination fails to specifically teach the limitation of the transparent material comprises a tinting agent. However, the combination teaches that the transparent material need not transmit all light (light transmission greater than 75 percent). If the transparent material does not transmit all light, there would be some type of tint blocking the rest of the light transmission. Therefore, the above combination does teach some type of tinting agent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731